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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/870,932

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Lijun Wu

MPI96-027CP2RCE2M

9497

30405

7590

05/26/2009

MILLENNIUM PHARMACEUTICALS, INC.

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EXAMINER

KOLKER, DANIEL E

ART UNIT

PAPER NUMBER

1649

MAIL DATE

DELIVERY MODE

05/26/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/870,932	Applicant(s) WU ET AL.	
	Examiner DANIEL KOLKER	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 158, 160-163, 166, 179, 181-184, 187, 200, 202-205 and 208 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 158, 160-163, 166, 179, 181-184, 187, 200, 202-205, 208 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The remarks filed 3 March 2009 have been entered. No claims were amended. Claims 158, 160 - 163, 166, 179, 181-184, 187, 200, 202-205, and 208 are pending and under examination.

Withdrawn Rejections

2. The rejection under 35 USC 103(a) is withdrawn in light of the arguments presented by applicant. At pp. 7 - 9 of the remarks filed 3 March 2009, applicant persuasively argues that the art of record, as a whole, teaches away from the second extracellular loop of CCR5 as being the principal region of the receptor that allows for HIV-1 entry.

Maintained Rejections

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 158, 160 - 163, 166, 179, 181-184, 187, 200, 202-205, and 208 stand rejected under 35 U.S.C. 102(e) as being anticipated by Combadiere (U.S. Patent Application Publication 2003/0195348, of record).

This rejection is maintained for the reasons of record. Applicant's attention is drawn to the office action mailed 4 September 2008, particularly pp. 7 - 8. Combadiere teaches "antibodies that bind CCR5 that block env-mediated membrane fusion (i) associated with HIV entry into a human CD4-positive target cell" (paragraph [0068]). Combadiere teaches that "[t]he invention also includes antibodies that bind to CCR5 and inhibit chemokine binding." Chemokines which bind to CCR5 are disclosed by Combadiere to include RANTES, MIP-1 α , and MIP-1 β (paragraph [0023]). The antibodies include those raised against the extracellular loops (paragraphs [0069] and [0089]), and Combadiere also discloses that the invention includes antibodies with "any or all of these [above-disclosed] functions" (paragraph [0069]).

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Thus the invention clearly includes those antibodies which inhibit chemokine binding and HIV entry, and which bind to the second extracellular loop, as recited in claim 158. The reference teaches monoclonal, chimeric, humanized, and human antibodies (see paragraphs [0072] - [0076]), as recited in claims 160 - 163, as well as specific antigen-binding fragments (see paragraph [0078]), as recited in claim 166. Claims 179, 181 - 184, and 187 are anticipated as Combadiere teaches compositions comprising the antibodies and physiologically acceptable carriers; see for example paragraph [0111]. Claims 200, 202 - 205, and 208 are anticipated as they require nothing other than the antibodies themselves.

At pp. 11 - 13 of the remarks filed 3 March 2009, applicant traverses this rejection. Specifically, applicant argues that Combadiere fails to teach every element of the claimed invention. Applicant makes the following points, each of which will be addressed in turn:

1) Combadiere only shows actual reduction to practice of a single antibody, raised against the N-terminus of CCR5 and not the second extracellular loop as claimed.

2) The disclosure of Combadiere is generic, and the reference does not actually disclose the antibodies now claimed, but lists a series of features which antibodies may or may not have.

Applicant's arguments have been fully considered but they are not persuasive. With respect to point 1), the examiner acknowledges that Combadiere provides more detailed description of the antibody raised against the N-terminus of CCR5 than some of the other antibodies disclosed in the publication. However, Combadiere indicates that the detailed examples are not the only embodiments of the specification, and that the detailed examples are not limiting (paragraph [0161]). Publications are valid as references for all that they teach, even non-preferred embodiments (MPEP § 2123(I)). With respect to point 2) above, the reference clearly discloses that antibodies against each of the extracellular loops are part of the invention (paragraph [0069]), and specifically teaches that the invention includes inhibitors that bind to CCR5 and simultaneously block binding of chemokines and HIV; see paragraph [0014]. The reference also teaches that antibodies include those raised against the second extracellular loop (paragraph [0069]). Clearly the reference teaches every feature of the antibodies now claimed, in that it teaches how to make antibodies, that the antibodies block binding of both HIV and chemokine ligands (paragraph [0014]), that the chemokines which are blocked are those recited in each of the independent claims of this application (paragraph [0023] for example), and that the antibodies include those against the second extracellular loop. Every feature of the claimed invention is taught by Combadiere.

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For the reasons above, the rejection under 35 USC 102(e) stands.

Conclusion

4. No claim is allowed.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL KOLKER whose telephone number is (571)272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel E. Kolker/

Primary Examiner, Art Unit 1649

May 21, 2009